

## **REMARKS/ARGUMENTS**

Claims 1-2 and 4-20 are currently pending with Claims 14-20 having been withdrawn from consideration. Claim 3 has been cancelled. Claim 1 has been amended by this response. It is respectfully submitted that the following remarks present no new issues or new matter and place this case in condition for allowance. Reconsideration of the application in view of the following remarks is respectfully requested.

### **I. Rejection of Claims 1-7 and 9-13 under 35 U.S.C. §102 (b)**

Claims 1-7 and 9-13 are rejected under 35 U.S.C. §102 (b) as being anticipated by Itoh et al. (U.S. Patent 6,221,402).

Itoh discloses a taste-masking composition comprising a core, an inner layer, outer layer, and a sugar layer. Itoh applies two coating layers to a core containing a pharmaceutically active ingredient. The inner coating of Itoh is formed from a combination of polymers. The polymers include cellulose polymers, which are not enteric coating polymers, and up to 30 weight percent of enteric coating polymers such as the methacrylate copolymer, Eudragit NE 30D, which are excluded from the inner coating of the claimed invention. In all of Examples 1-5 of Itoh, the inner layer is a mixture of hydroxypropyl methyl cellulose and Eudragit NE-30D. Itoh does not provide any working examples disclosing an inner coating layer containing only cellulose polymers. Thus, the inner coating layer of Itoh is substantially different from applicants' inner coating layer.

Applicants have amended Claim 1 to recite an inner coating consisting essentially of at least one cellulose polymer selected from the group consisting essentially of hydroxypropyl-methyl cellulose, hydroxypropyl cellulose, methyl cellulose, ethyl cellulose, carboxymethylethyl cellulose, sodium carboxymethyl cellulose, ethylcarboxyethyl cellulose, and combinations thereof. Support can be found in applicants' originally filed Claim 3. Through the use of "consisting essentially of" language, applicants' have excluded the use of other non-cellulose polymers such as methacrylate copolymers that would materially affect the basic and novel characteristics of applicants' invention as claimed.

For the reasons set forth above, It is submitted that Itoh does not anticipate applicants' Claims 1-7 and 9-13 under 35 U.S.C. §102 (b) and withdrawal of this ground of rejection is respectfully requested.

### **II. Rejection of Claim 8 under 35 U.S.C. §103**

Claim 8 is rejected under 35 U.S.C. 103 as being obvious over Itoh et al. in view of Ullah et al. (U.S. Patent 6,331,316). The rejection is respectfully traversed.

As discussed in the above rejection under 35 U.S.C. § 102 (b), Itoh discloses an inner coating formed from a combination of cellulose polymers and up to 30 weight percent of enteric coating polymers. Use of the enteric coating polymers in the inner coating would likely increase the dissolution time leading to a reduction in the bioavailability of Itoh's composition. Therefore, it is clear that Itoh does not anticipate applicants' invention as claimed, but it also teaches away from the claimed invention.

Ullah is directed to a composition which employs a single coating layer which is an enteric coating layer. Ullah specifically teaches that a goal of the invention is the elimination of protective coats or subcoatings by adjusting the pH of the enteric coating suspension (Col. 4, lines 26-29 and Col. 7, lines 11-17). Since applicants' invention as claimed comprises both an inner coating layer and an outer enteric coating layer, Ullah teaches away from applicants' invention as claimed.

The motivation or suggestion to combine references in the manner suggested by the Examiner must come from the applied references. There is no disclosure, direction, or motivation in either Itoh or Ullah to suggest the combination asserted by the Examiner. There is no motivation in the art for one skilled to combine Itoh with Ullah as suggested by the Examiner. Ullah states in column 7, lines 11-14 "the novel pharmaceutical composition of the present invention, as a result of the novel process utilized in the making of the composition of the present invention and the pH adjustment of the coating does not require a subcoat." One skilled in the art would conclude that Ullah has provided a successfully working composition, and there would be not motivation to combine any part of Itoh's composition to Ullah's composition.

Assuming *arguendo*, even if motivation to combine the references in the manner suggested by the Examiner did exist in the applied references, the resultant combination still would not disclose applicants' claimed invention. One skilled in the art would conclude from the teachings of both Itoh and Ullah that an enteric coating polymer (i.e. Eudragit) is an essential component in the inner coating layer. Applicants' invention as claimed does not include an enteric coating polymer in the inner coating, and through the use of "consisting essentially of" language in Claim 1, applicants have excluded the use of an enteric coating polymer that would materially affect the basic and novel characteristics of applicants' invention as claimed. Thus, the Examiner has not established a *prima facie* case for obviousness under 35 U.S.C. §103.

### **III. Provisional Double Patenting Rejection**

Claims 1-8 and 12-13 are provisionally rejected for double patenting based upon the claims of co-pending application serial number 10/768,562.

It is noted that the '562 application is a continuation-in-part of the present application and was filed several months after the present application. Further, applicants have not yet received a substantive Office Action from the Patent Office in regard to the '562 application. Thus, the

current case is further along in prosecution and currently appears likely to advance to an allowance prior to the '562 application. Accordingly, applicants prefer to refrain from amending the claims in the present case, but will, if necessary, amend the claims in the '562 application at a later time in order to avoid any alleged double patenting difficulties arising from the two applications.

In view of the above, it is respectfully submitted that all of the claims are in condition for allowance, and a Notice of Allowance is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

  
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Date: Feb. 9, 2007